

PCT

WORLD INTELLECTUAL PROPERTY ORGANIZATION
International Bureau

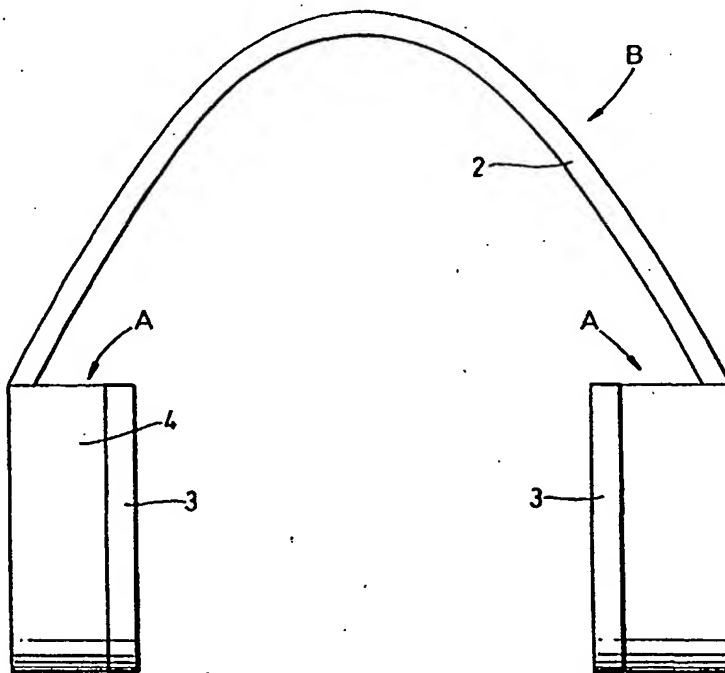
INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

| | | | |
|---|--|--|--|
| (51) International Patent Classification 7 : A61N 5/06 | | A1 | (11) International Publication Number: WO 00/35534 |
| | | | (43) International Publication Date: 22 June 2000 (22.06.00) |
| (21) International Application Number: PCT/GB99/04189 | | (81) Designated States: AE, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CU, CZ, DE, DK, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, UA, UG, US, UZ, VN, YU, ZA, ZW, ARIPO patent (GH, GM, KE, LS, MW, SD, SL, SZ, TZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG). | |
| (22) International Filing Date: 10 December 1999 (10.12.99) | | | |
| (30) Priority Data: 9827339.4 12 December 1998 (12.12.98) GB 9915898.2 8 July 1999 (08.07.99) GB | | | |
| (71) Applicant (for all designated States except US): VIRULITE LIMITED [GB/GB]; P.O. Box 210, Darlington DL3 9GZ (GB). | | | |
| (72) Inventor; and (75) Inventor/Applicant (for US only): DOUGAL, Gordon, Rex, Harrison [ZA/GB]; Hartlepool General Hospital, Holdford Road, Hartlepool TS24 9AH (GB). | | | |
| (74) Agent: HARRISON GODDARD FOOTE; Belmont House, 20 Wood Lane, Leeds LS6 2AE (GB). | | Published. With international search report. | |

(54) Title: ELECTROMAGNETIC RADIATION THERAPY

(57) Abstract

The present invention discloses an apparatus for emitting electromagnetic radiation of between 980 and 1350 nm to skin covering skull, temple regions and/or frontal lobes of an individual's head, the apparatus comprising means for emitting electromagnetic radiation and being capable of producing, at the site being treated, a radiation intensity of at least 15 mWatts/cm² and up to 10 Watts/cm².



BEST AVAILABLE COPY

FOR THE PURPOSES OF INFORMATION ONLY

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

| | | | | | | | |
|----|--------------------------|----|--|----|--|----|--------------------------|
| AL | Albania | ES | Spain | LS | Lesotho | SI | Slovenia |
| AM | Armenia | FI | Finland | LT | Lithuania | SK | Slovakia |
| AT | Austria | FR | France | LU | Luxembourg | SN | Senegal |
| AU | Australia | GA | Gabon | LV | Latvia | SZ | Swaziland |
| AZ | Azerbaijan | GB | United Kingdom | MC | Monaco | TD | Chad |
| BA | Bosnia and Herzegovina | GE | Georgia | MD | Republic of Moldova | TG | Togo |
| BB | Barbados | GH | Ghana | MG | Madagascar | TJ | Tajikistan |
| BE | Belgium | GN | Guinea | MK | The former Yugoslav Republic of Macedonia | TM | Turkmenistan |
| BF | Burkina Faso | GR | Greece | ML | Mali | TR | Turkey |
| BG | Bulgaria | HU | Hungary | MN | Mongolia | TT | Trinidad and Tobago |
| BJ | Benin | IE | Ireland | MR | Mauritania | UA | Ukraine |
| BR | Brazil | IL | Israel | MW | Malawi | UG | Uganda |
| BY | Belarus | IS | Iceland | MX | Mexico | US | United States of America |
| CA | Canada | IT | Italy | NE | Niger | UZ | Uzbekistan |
| CF | Central African Republic | JP | Japan | NL | Netherlands | VN | Viet Nam |
| CG | Congo | KE | Kenya | NO | Norway | YU | Yugoslavia |
| CH | Switzerland | KG | Kyrgyzstan | NZ | New Zealand | ZW | Zimbabwe |
| CI | Côte d'Ivoire | KP | Democratic People's Republic of Korea | PL | Poland | | |
| CM | Cameroon | KR | Republic of Korea | PT | Portugal | | |
| CN | China | KZ | Kazakhstan | RO | Romania | | |
| CU | Cuba | LC | Saint Lucia | RU | Russian Federation | | |
| CZ | Czech Republic | LI | Liechtenstein | SD | Sudan | | |
| DE | Germany | LK | Sri Lanka | SE | Sweden | | |
| DK | Denmark | LR | Liberia | SG | Singapore | | |
| EE | Estonia | | | | | | |

ELECTROMAGNETIC RADIATION THERAPY

Field of the Invention

5 This invention relates to an apparatus producing, and a method of therapy using, electromagnetic radiation for the treatment of neurological and psychiatric conditions. The invention may be used in connection with the cure or alleviation of symptoms associated with neurological and psychiatric conditions such as depression, stress, anxiety, cerebral oedema/trauma, sexual dysfunction, dementia
10 and neurodegenerative conditions such as Parkinson's disease.

Background of the Invention

Current medically accepted methods of treating neurological and psychiatric
15 conditions involves the administration of pharmacologically active products typically taken orally which reaches the brain via the circulation. Such treatments have many side effects, not only centrally with sedation but adverse side effects on other organs/tissues such as the gastrointestinal tract and bone marrow have been documented.

20

The cerebrum, which is encased and protected by the skull, is part of the neurological system. The cerebrum is a highly complex and incompletely understood organ. Amongst its many functions, it deals with personality, emotion, mood, evaluation of sensory input and initiation of motor output. The cerebrum is associated with the
25 spinal cord and cranial nerves these nerves being involved with the senses of hearing, balance, sight, smell and also provide sensory and motor function of the head and neck.

It is generally accepted that the brain and retina begins to naturally functionally decay
30 after the age of 35 years, however since the brain and retina have, like other organs, significant redundant capacity, the individual is able to function normally until such

time as the redundant capacity is exhausted. This decay process is insidious and goes unnoticed and is often associated with poor fine-motor control starting in the 6th and 7th decades of life, hence evaluation of patients handwriting during assessment of cognitive function.

5

It has been known for several decades that the use of light can give a positive therapeutic effect in the treatment of a wide spectrum of typically topical diseases. In the 1960's the use of narrow wavelength light was investigated in *in vivo/in vitro* experiments. It was found that light of wavelength greater than 440nm did not work.

10 Further investigations were carried out with light having a wavelength of from 300 to 350nm (UV light) but it was found that infection was exacerbated/promoted rather than ameliorated/eliminated. Some attempts have been made to treat individuals affected with the herpes virus by treatment with light of the wavelength 660nm, as described in US 5500009.

15

Additionally, it is known from the prior art to use a laser to produce coherent radiation and to focus it on the area to be treated. Nd YAG laser treatment at a fundamental wavelength of 1064 nm is associated with decreased pain, scarring and improved healing (US 5445146). Additionally it has been reported that diodes emitting light at the red wavelength, 940 ± 25 nm can be used to treat a range of essentially musculoskeletal ailments (US 5259380). However there is no indication that light of a wavelength above this would be of any therapeutic use. Moreover there has been no indication in the prior art that light would have any effect on bone and or cartilage beneath the skin.

20

25 It has now been surprisingly established that low intensity electromagnetic radiation of narrow bandwidth light, when applied to the skin overlying the skull penetrates the skull bone and has an unexpected therapeutic effect on the underlying brain tissue itself and is effective in the treatment of treating neurological and psychiatric conditions in addition to rejuvenating the individual. It is postulated that the way in which the electromagnetic radiation effects its action is by way of energy

30

transmission through cellular components/organelles and may involve an alteration in neuronal membranes.

5 A water molecule that has a range of electromagnetic radiation wavelengths passed through it will produce several transmission peaks. These transmission peaks are associated with the preferred therapeutic electromagnetic radiation wavelength range of the invention and thus implies a role for the water molecule in the general mechanism of action.

10 **Statements of the Invention**

According to a first aspect of the present invention there is provided an apparatus for electromagnetic radiation therapy comprising means for emitting electromagnetic radiation being a wavelength of from 980 and 1350 nm, a patient attachment means
15 whereby said apparatus is securable to a patient with said electromagnetic radiation emitting means being positioned adjacent bone which surrounds tissue of the central nervous system and so that radiation emitted from the electromagnetic radiation emitting means is directed towards said tissue, said electromagnetic radiation emitting means being capable of producing a radiation intensity of at least 15
20 mWatts/cm² and up to 10 Watts/cm² at the skin covering said bone.

Reference herein to a skin covering bone surrounding the central nervous system is intended to include, without limitation, the skin surrounding the skull, frontal and temporal areas, occipito parietal junction and base of the skull overlying the brain
25 stem, spinal column and peripheral nerves of a human or animal subject. It will be appreciated that the present invention provides an apparatus for treating any part of the neurological system which is covered by bone.

Preferably, the apparatus comprises a plurality of means for emitting electromagnetic
30 radiation and more preferably each of said means is independently controllable.

Preferably, the apparatus is adapted so that it is worn on or about the individual's head. In one embodiment of the invention the apparatus comprises a pair of means for emitting electromagnetic radiation attached to either end of a curved, resilient bridge member. Preferably, the bridge member is an elongate strip composed of a suitable material such as plastics. Thus, in this embodiment the apparatus is in the form of a headset with light emitting sources positioned at either end which can be appropriately positioned about the user's head. In use, the means for emitting electromagnetic radiation are appropriately aligned with an individual's temple regions. It will be understood that preferably, the headset may be worn over the top, or around the front or back of a user's skull.

In another embodiment of the invention the apparatus is in the form of a helmet in which the means for emitting electromagnetic radiation are placed on an inside surface of the helmet.

Preferably, the headset and helmet are provided with means for shielding a user's eyes. For example, with the headset the means for emitting electromagnetic radiation may be encased within housing units/compartments which are attached to either end of the bridge means. Alternatively, where the apparatus is a helmet, the helmet may be provided with an inwardly protruding flange composed of an opaque resilient material which effectively seals the individual's skin around the area of contact. In this way egress of light from the interior of the helmet is prevented.

Preferably, the apparatus is provided with cooling means such as fans, thermoelectric/peltier devices or the like so as to prevent the means for emitting electromagnetic radiation overheating.

Preferably, the apparatus of the invention is portable.

It will be appreciated that the apparatus of the invention can be used to direct light to via the transcutaneous transosseous route of the skull but that areas of the skull

substantially bereft of hair, such as the forehead/frontal lobes and/or temple regions are the preferred sites to receive light because the presence of hair can reduce and/or scatter the light and effect the power intensity at the treatment site.

- 5 Preferably the wavelength of the electromagnetic radiation is in the range 980nm-1300nm. A particularly preferred wavelength is at, or about, 1072nm. A yet further particularly preferred wavelength is at, or about, 1268nm.

Our studies have shown that the wavelength centred around 1072 nm is particularly
10 effective at treating neurological and psychiatric conditions. It is of note that the two preferred wavelengths correspond to the peak emission wavelengths of a water molecule light transmission profile and thus we believe that the mechanism of action is related to water and possibly cell membranes.

- 15 Preferably, the electromagnetic radiation is divergent and more preferably is at least 5° and up to 40° half angled divergent.

By divergent it meant that the electromagnetic radiation emitted from the system of the invention has a divergent half angle of at least 5°. Preferably divergence of the
20 electromagnetic radiation is in the range 15° to 40° half angled divergent.

Preferably the electromagnetic radiation is continuous or pulsed.

- Preferably when the electromagnetic radiation is continuous the intensity is at least
25 15 mWatts/cm² and up to 2 Watts/cm², and more preferably is in the range 300 -700 mWatts/cm², most preferably it is 500mWatts/cm².

- Preferably when the electromagnetic radiation is pulsed the intensity is at least 20 mWatts/cm² peak power and up to 10 Watts/cm², and more preferably is in the range
30 300 -700 mWatts/cm², most preferably it is 500mWatts/cm².

The average power is the peak power multiplied by the proportion of the total time that the radiation is applied. For instance if the peak power is 500 mWatts/cm² and is pulsed for 10 μseconds at a frequency of 600 Hz then the average power is 3m Watts/cm².

5

Preferably when the electromagnetic radiation is pulsed the average power of the intensity is in the region of 50-100 mWatts/ cm².

Preferably when the electromagnetic radiation is pulsed it is applied for periods of at least 30 seconds and more preferably is applied at a frequency/repetition rate in the range 480-800 Hz more preferably still the frequency/repetition rate is at, or about, 600 Hz.

Our studies have shown that the electromagnetic radiation can be either coherent or non-coherent the clinical outcomes are not affected by this parameter.

It should be appreciated that the power source emitting the electromagnetic radiation will have to produce more than the required intensity for the clinical effect since we have shown that approximately 99% of the applied therapeutic amount of light is lost across the skin surface during treatment. Thus the intensity of applied radiation will have to be corrected for when carrying out a treatment.

From the foregoing it is understood that the electromagnetic radiation may be directed to the target site either continuously or in a switched (pulsed) manner. The main benefit of switching enables power conservation and facilitates much higher peak power output, thereby improving clinical response.

Preferably, the apparatus also includes means for reducing the amount of ambient radiation which impinges on the site to which the electromagnetic radiation is applied.

Preferably the apparatus further includes means for fixing the intensity of the radiation within a pre-determined range. The radiation output may be monitored with a visible display indicating correct function of the device both for intensity and wavelength.

5

Preferably the apparatus includes means for controlling the duration of the application of the radiation. Accordingly, the present invention is concerned with the use of electromagnetic radiation having a wavelength in the range from visible to infra red and applied at a low intensity such that no thermal damage is caused to any human or animal tissues.

10

The radiation producing means are preferably solid state light emitting devices, more preferably solid state light emitting diodes, gas discharge devices or lasers such as YAG lasers.

15

Preferably, the radiation emitter includes a PN junction arranged to emit radiation with a wavelength centring at or about 1072nm or at or about 1268 nm. A single light diode assembly may include a plurality of orientated junctions.

20

Infrared emitting diodes may be arranged not only to emit radiation at a specific frequency but also to emit a high intensity divergent beam.

A gas discharge device may include a mixture of gases which will give an output at the desired wavelength, for instance, 1072 nm.

25

Another preferred radiation producing means is a laser diode device, an example being a laser diode emitting light at a frequency of 1072 nm. Such a light emitting means is of low power intensity having a divergent beam and not giving rise to thermal damage.

30

The present invention also provides the use of electromagnetic radiation having a wavelength of between 980 and 1350 nm and an intensity of at least 15 mWatts/cm² and up to 10 Watts/cm² to treat neurological and/or psychiatric conditions.

- 5 Preferably the electromagnetic radiation as produced by the apparatus of the invention includes any one or more of the preferred features herein before described and more preferably provides for use of electromagnetic radiation in the treatment of conditions such as, without limitation, depression, stress, anxiety, cerebral oedema/trauma, sexual dysfunction, memory loss, dementia and neurodegenerative
10 conditions such as Parkinson's disease.

- The present invention also provides a method of treating an individual suffering from a neurological and/or psychiatric condition comprising applying electromagnetic radiation to an area of an individual's head, neck or spine electromagnetic radiation
15 having a wavelength of between 980 and 1500 nm at an intensity of at least 15 mWatts/cm² and up to 10 Watts/cm².

- Preferably, the area to be treated is irradiated so that the skin surrounding the skull or spinal column receives at least 300-700 mWatts/cm² peak power of radiant energy.
20 A factor here is the period of irradiation and, preferably, the period should be at least a specified minimum of 30 seconds at a repetition rate /frequency of 450-800 Hz and preferably for at least two consecutive days and up to several months more preferably still the treatment is over several weeks.

- 25 Preferably, the electromagnetic radiation is applied to the affected area for at least a few minutes and up to an hour. A typical exposure time is in the region of 3 minutes per day.

- Preferably, the electromagnetic radiation is applied for at least two consecutive days
30 and up to several weeks depending on the nature and severity of the condition.

Preferably, after a first course of electromagnetic radiation has been applied a second or subsequent course is applied over a period of several months, typically it is applied every month or so or twice yearly depending on the severity and nature of the condition.

5

Preferably, the area to be treated is substantially the skin around the skull, spinal column and/or neck and more preferably is of several cm² in area.

According to a yet further aspect of the invention there is provided a radiation emitting means in the manufacture of an apparatus for electromagnetic radiation therapy for use in the treatment of neurological and/or psychiatric disorders, said means for emitting electromagnetic radiation being capable of emitting radiation having a wavelength of from 980 to 1350 nm.

15 **Brief Description of the Drawings**

Embodiments of the invention will now be described, by way of examples only, and with reference to the accompanying drawings, in which: -

Figure 1 represents an electromagnetic radiation emitting source of a first embodiment of an apparatus in accordance with the present invention;

Figures 2 represents a front view of a first embodiment of an apparatus in accordance with the present invention;

Figures 3 represents a front view of an apparatus of a second embodiment of the present invention; and

Figures 4 represents a side cross sectional view of Figure 3 of an apparatus of a second embodiment of the present invention;

Detailed Description of Preferred Embodiments

Referring to Figures 1 there is shown a means for emitting electromagnetic radiation A. The means being a solid state light emitting device such as a solid state light emitting diode or a gas discharge device or a laser such as a YAG laser. Typically

the light emitted is $1072 \pm 100\text{nm}$. In use, the light sources can be held in position against an individual's temple region separately but a preferred embodiment of the invention provides a pair of means for emitting electromagnetic radiation A connected together.

5

The means for emitting electromagnetic radiation A comprises a central portion 1 which emits the light and a perimeter or peripheral region 3. Region 3 is raised with respect to region 1 and is constructed of a suitably soft and opaque material such as foam so as to prevent light escaping beyond region 3 whilst providing comfort for the user.

10

The apparatus of the first embodiment of the invention provides a headset arrangement B as depicted in Figure 2. The apparatus comprises a pair of light emitting means A housed within units 4, each unit being connected via a bridge member 2. The bridge member is shaped so that it may be worn about an individual's head. The bridge means is typically composed of a resilient material such as plastics and it can be worn over the top, around the back or across the forehead of an individual. Housed within units 4, the apparatus may be provided with cooling fans thermoelectric/peltier devices or the like (not shown) so as to prevent the means for emitting electromagnetic radiation overheating. In use and when worn the units 4 containing the light emitting means are positioned so that the perimeter or peripheral region 3 is in contact with the user's skin typically over the temple region of the skull. Light treatment is carried out for a pre-set predetermined period after which the light sources can be removed or rotated/moved around the head to another treatment site.

15

20

25

The apparatus emits a single wavelength at any one time, preferably in the infrared spectrum. However, the effective wavelengths, which may be covered by such an apparatus, extend from the visible spectrum to the infrared. In another embodiment of the invention, two wavelengths are used, one that is visible and the other that is invisible, particularly in the case where the optimal wavelength is in the infrared.

30

The radiation source is provided with two On/Off switches (not shown), which may be actuated to initiate the operation of the internal electronics. Both switches have to be pressed simultaneously in order to operate the device correctly, thereby preventing
5 inadvertent use of the device.

The radiation source is provided with control electronics (not shown), which limit the time that the radiation source is on and then automatically switches off the radiation source. The control electronics monitor the ambient radiation and, in the event that
10 the ambient radiation is of an intensity that would interfere with the therapeutic effect of the radiation source, an alarm buzzer (not shown) sounds.

With reference to Figures 3 and 4 there is shown a front view and a side cross sectional view respectively of a second embodiment C of the apparatus of the present
15 invention. In this embodiment, the apparatus is a helmet designed to be worn substantially over an individual's head. The helmet is therefore shaped accordingly and is domed. It is provided with an array of light sources directing light to an inner surface 4 of the helmet. When worn, the areas of the helmet corresponding to an individual's forehead and temple region 5 are provided with light sources of higher
20 optical power density. The helmet is also provided with a protrusion 6 in the form of resilient opaque material such as foam so as to prevent egress of light from the helmet interior thus protecting the eyes of the individual to be treated. The helmet is also provided with cooling fans or the like to prevent the light emitting means from over-heating. In this embodiment the whole area of the brain may be treated
25 simultaneously. Alternatively selected areas may be treated, thus it will be appreciated that the array of light emitting units within the helmet may be independently controlled for both power intensity and duration.

Experimental Results

Examples of the invention will now be described with reference to the treatment of particular conditions.

5

Dementia

The study group comprised 5 patients suffering from dementia and with average Mini Mental Test Scores 10/30. Treatment was focused over the frontal, temporal and parietal lobes at a light intensity of between 500 $\mu\text{Watts/cm}^2$ to 10 Watts/cm^2 for 8 minutes. The higher light is preferably pulsed which does not impair efficacy. However, we have found that a direct correlation in the surface area of skin receiving light and efficacy of treatment, moreover efficacy can be further improved by simultaneously treating different sites. The treatment was applied on three consecutive days initially and subsequently for twice weekly over a period of eight weeks. We found that at the end of the treatment protocol the average Mini Mental Test Scores was 20/30.

In Alzheimer's dementia there is neuronal degeneration with associated impairment of cellular function including the impaired production of neurotransmitters. Initial treatment of an individual using the apparatus of the invention causes a release of neurotransmitters into the synaptic cleft where they are taken up again and/or degraded. The extra release of neurotransmitters is manifest by a slight increase in activity for the period of 18 hours post-treatment, however this is followed by a slight decline in function for the period 24-48 hours post-treatment. We have found that to achieve maximal stimulation of cell repair and regeneration a subsequent treatment is required during this period.

The results from the five study patients indicate that the apparatus and method of treatment of the invention has the capability of improving degenerative conditions such as dementia and causing overall rejuvenation. The improvements observed in

the Mini Mental Test Scores before and after treatment imply that this invention has use in treating individuals suffering from dementia. Moreover, it offers the advantage of allowing dementia suffers to remain in the community as opposed to institutionalised care. Thus, the present invention would also be of benefit to the health and medical services in that the invention offers a simple and inexpensive therapy to dementia sufferers and will reduce the demand for more expensive and resource draining permanent institutional care.

Parkinson's Disease

10

A single male subject suffering from Parkinson's disease was treated over the frontal and temporal areas, occipito parietal junction and base of the skull overlying the brain stem. The duration of the therapy was 8 minutes on each area on two consecutive days per week.

15

After the first week of treatment the patient reported, by subjective evaluation, that he felt an improvement in his general condition. Objective evaluations over several weeks showed that the patient suffered less facial spasms and less tremor whilst asleep. Further light treatments were associated with progressive improvements it was estimated that the light therapy had reversed the progression of the disease by some 6-8 months.

20

Depression

Depression is an extremely common disorder affecting the majority of the population at some time in their lifetime. The study group comprised 7 individuals, the treatment protocol adopted for the clinically depressed individuals was as follows:

25

Treating the frontal and temple regions of the skull for 15 minutes twice daily initially reducing treatment time to 8 minutes once a day once clinical resolution had occurred. Thereafter treatment was given for 8 minutes once a week.

30

As with previous pathologies there can be a transient worsening of mood initially for the first 1-2 treatments. However, a rapid improvement in mood was observed after the first week to a point of euthymia. Motivation and concentration were found to
5 improve after 72 hours of the first treatment.

Sexual Dysfunction

The study group comprised 10 males and 5 females.

10

Light at 1072nm appears to have its effect by the release of neurotransmitters in the brain which are responsible for sexual arousal in both male and female. In the male this results in an increased basal blood flow through the genitals, especially the penis with an associated increase in volume of the testes. As the basal blood flow of the
15 penis is higher the threshold for an arousal response is lowered resulting in sustained erection. In the female, the neurotransmitter release is associated with an increase in vaginal secretions. Light at 1072nm is associated with ongoing intracellular production of these neurotransmitters to an optimal level which results in a sustained improvement in sexual function in both males and females.

Claims

1. An apparatus for electromagnetic radiation therapy comprising means for emitting electromagnetic radiation being a wavelength of from 980 and 1350 nm, a
5 patient attachment means whereby said apparatus is securable to a patient with said electromagnetic radiation emitting means being positioned adjacent bone which surrounds tissue of the central nervous system and so that radiation emitted from the electromagnetic radiation emitting means is directed towards said tissue, said electromagnetic radiation emitting means being capable of producing a radiation
10 intensity of at least 15 mWatts/cm² and up to 10 Watts/cm² at the skin covering said bone.
2. An apparatus according to Claim 1 wherein the apparatus comprises a plurality of means for emitting electromagnetic radiation.
- 15 3. An apparatus according to either preceding claim wherein each of the means for emitting electromagnetic radiation is independently controllable.
4. An apparatus according to any preceding claim wherein the apparatus is
20 adapted so that it is worn on or about the patient/individual's head.
5. An apparatus according to any preceding claim wherein the apparatus comprises a pair of means for emitting electromagnetic radiation attached to either end of a curved, resilient bridge member.
- 25 6. An apparatus according to Claim 5 wherein the bridge member is an elongate strip composed of a suitable material such as plastics.
7. An apparatus according to either of Claims 5 or 6 wherein the means for
30 emitting electromagnetic radiation are aligned with an individual's temple regions.

8. An apparatus according to any of Claims 5-7 wherein the apparatus is worn over the top or around the front or back of a patient's skull.
9. An apparatus according to any of Claims 1-4 wherein the apparatus is a
5 helmet in which the means for emitting electromagnetic radiation are placed on an inside surface of the helmet.
10. An apparatus according to any preceding claim wherein the apparatus is provided with means for shielding a user's eyes for electromagnetic radiation.
- 10 11. An apparatus according to any of Claims 5-7 or 10 wherein the means for emitting electromagnetic radiation are encased within housing units/compartments which are attached to either end of the bridge means.
- 15 12. An apparatus according to any of Claims 8-10 wherein the helmet is provided with an inwardly protruding flange composed of an opaque resilient material which effectively seals the individual's skin around the area of contact whereby light is prevented from escaping from the interior of the helmet.
- 20 13. An apparatus according to any preceding claim wherein the apparatus is provided with cooling means such as fans, thermoelectric/peltier devices or the like so as to prevent the means for emitting electromagnetic radiation overheating.
- 25 14. An apparatus according to any preceding claim wherein the apparatus is portable.
15. An apparatus according to any preceding claim wherein the apparatus emits electromagnetic radiation in the wavelength range of 980nm-1300nm.

16. An apparatus according to Claim 15 wherein the apparatus emits electromagnetic radiation of the wavelength at, or about, 1072nm and/or at, or about, 1268nm.
- 5 17. An apparatus according to any preceding claim wherein the electromagnetic radiation is divergent.
18. An apparatus according to Claim 19 wherein the electromagnetic radiation is at least 5° and up to 40° half angled divergent.
- 10 19. An apparatus according to any preceding claim wherein the electromagnetic radiation is continuous or pulsed.
- 20 An apparatus according to any preceding claim wherein when the
15 electromagnetic radiation is continuous the intensity is at least 15 mWatts/cm² and up to 2 Watts/cm².
21. An apparatus according to Claim 20 wherein the intensity is in the range 300 - 700 mWatts/cm².
- 20 22. An apparatus according to either Claim 20 or 21 wherein the intensity is 500mWatts/cm².
23. An apparatus according to any of Claims 1-19 wherein the pulsed
25 electromagnetic radiation intensity is at least 20 mWatts/cm² peak power and up to 10 Watts/cm².
24. An apparatus according to Claim 23 wherein the intensity is in the range 300 - 700 mWatts/cm²,
- 30

25. An apparatus according to either Claim 23 or 24 wherein the intensity is 500mWatts/cm².
26. An apparatus according to any of Claims 23-25 wherein the pulsed
5 electromagnetic radiation average power of the intensity is in the region of 50-100 mWatts/ cm².
27. An apparatus according to any of Claims 23-26 wherein pulsed
electromagnetic radiation is applied for periods of at least 30 seconds at a
10 frequency/repetition rate in the range 480-800 Hz.
28. An apparatus according to Claim 27 wherein the frequency/repetition rate is at, or about, 600 Hz.
- 15 29. An apparatus according to any preceding claim which further includes any one or more of the following features:
- (i) means for reducing the amount of ambient radiation which impinges on the site to which the electromagnetic radiation is applied;
 - (ii) means for fixing the intensity of the radiation within a pre-determined
20 range; and
 - (iii) means for controlling the duration of the application of the radiation.
30. An apparatus according to any preceding claim wherein the means for emitting electromagnetic radiation are solid state light emitting devices such as solid
25 state light emitting diodes, gas discharge devices or lasers such as YAG lasers.
31. An apparatus according to Claim 30 wherein the means for emitting electromagnetic radiation includes at least one PN junction arranged to emit radiation with a wavelength centring at or about 1072nm or at or about 1268 nm.

32. Use of electromagnetic radiation having a wavelength of between 980 and 1350 nm to treat neurological and/or psychiatric conditions.

33. Use of electromagnetic radiation according to Claim 32 wherein radiation
5 intensity of at least 15 mWatts/cm² and up to 10 Watts/cm² is produced at skin covering bone surrounding central nervous system tissue.

34. Use of electromagnetic radiation according to either of Claims 32 or 33 and further including any of the features of the apparatus of Claims 1-31.

10

35. Use of electromagnetic radiation according to any of Claims 32-34 for the treatment of depression, stress, anxiety, cerebral oedema/trauma, sexual dysfunction, memory loss, dementia and neurodegenerative conditions such as Parkinson's disease.

15

36. A method of treating an individual suffering from a neurological and/or psychiatric condition comprising applying electromagnetic radiation to at least a part of bone which surrounds tissue of the central nervous system so that radiation emitted from the electromagnetic radiation emitting means is directed towards said
20 tissue and wherein a radiation intensity of at least 15 mWatts/cm² and up to 10 Watts/cm² is produced at the skin covering said bone, the electromagnetic radiation having a wavelength of from 980 to 1350 nm.

37. A method of treatment according to Claim 36 wherein the area to be treated is
25 irradiated so that the skin covering bone which surrounds the central nervous system receives at least 300-700 mWatts/cm² peak power of radiant energy.

38. A method of treatment according to either of Claims 36 or 37 wherein the duration of treatment is at least 30 seconds at a repetition rate /frequency of 450-800
30 Hz.

39. A method of treatment according to any of Claims 36-38 wherein the duration of treatment is up to several hours per day.

40. A method of treatment according to Claim 39 wherein the duration of
5 treatment is between 3-15 minutes per day.

41. A method of treatment according to any of Claims 36-40 wherein the treatment is applied for at least two consecutive days and weekly up to several months.

10

42. Use of a radiation emitting means in the manufacture of an apparatus for electromagnetic radiation therapy for use in the treatment of neurological and/or psychiatric disorders, said means for emitting electromagnetic radiation being capable of emitting radiation having a wavelength of from 980 to 1350 nm.

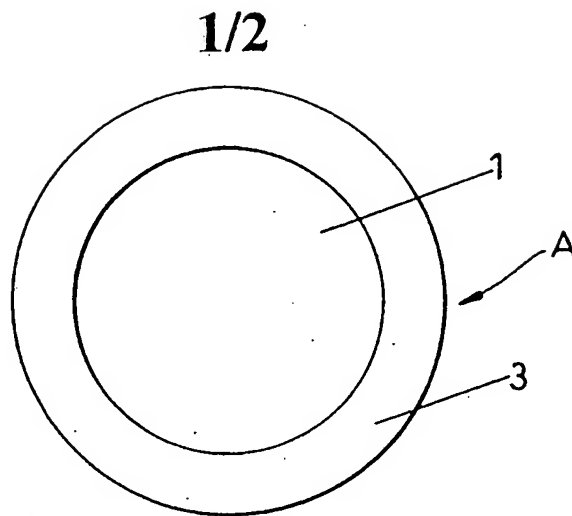


Fig. 1

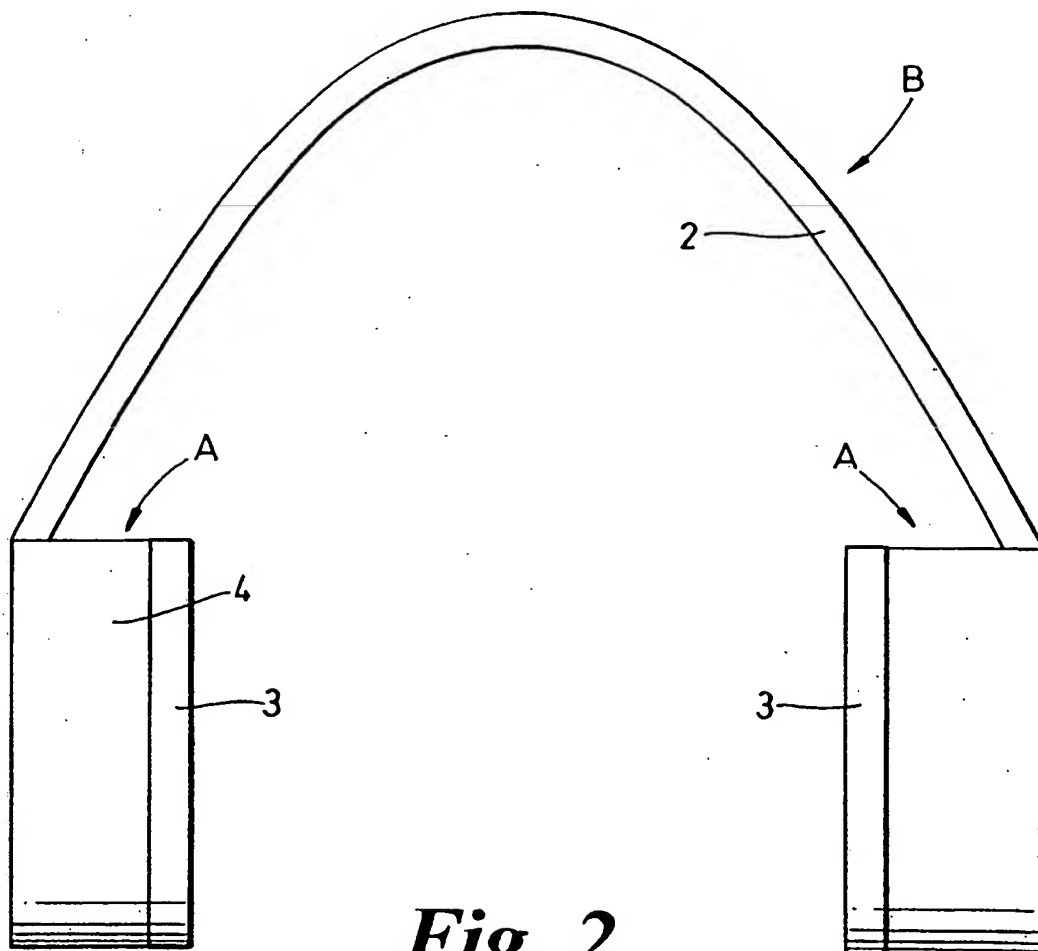


Fig. 2

2/2

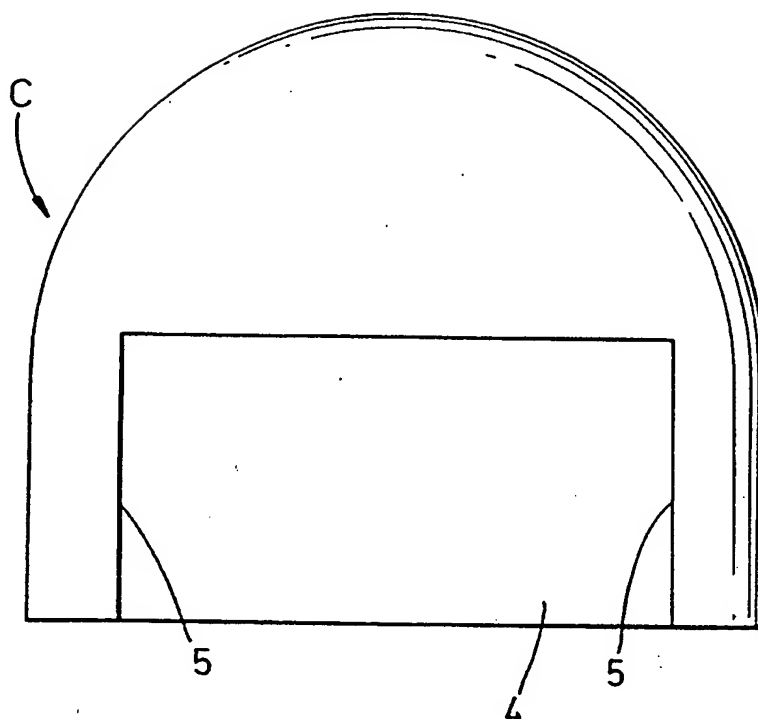


Fig. 3

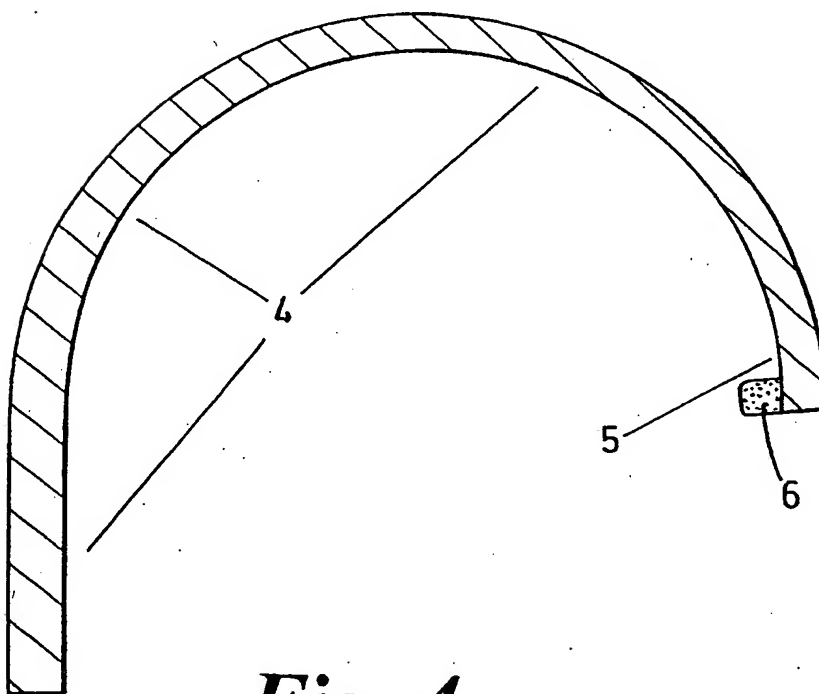


Fig. 4

INTERNATIONAL SEARCH REPORT

Inter. Appl. No.

PCT/GB 99/04189

A. CLASSIFICATION OF SUBJECT MATTER

IPC 7 A61N5/06

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 7 A61N

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

| Category * | Citation of document, with indication, where appropriate, of the relevant passages | Relevant to claim No. |
|------------|--|-------------------------|
| X | WO 98 30283 A (LASER BIOTHERAPY INC) 16 July 1998 (1998-07-16) page 5, line 1 - line 12 page 8, line 14 - line 23 | 1, 30, 31, 42 |
| Y | | 2-4, 8, 9, 12, 14-29 |
| Y | DE 295 15 096 U (WILDEN LUTZ DR MED) 30 November 1995 (1995-11-30) page 4, line 1 - page 7, line 16 | 2-4, 8, 9, 12, 14-29 |
| A | DE 28 26 353 A (GORBAHN FRITZ DR MED) 20 December 1979 (1979-12-20) page 15, line 23 - line 31; figure 8 | 5-7, 11 |
| A | DE 41 13 803 A (IWG EASTMED MEDIZINTECHNIK GMB) 29 October 1992 (1992-10-29) column 1, line 50 - column 2, line 20 | 13 |
| | -/- | |

☒ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

* Special categories of cited documents:

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"A" document member of the same patent family

Date of the actual completion of the international search

24 March 2000

Date of mailing of the international search report

04/04/2000

Name and mailing address of the ISA

European Patent Office, P.B. 5818 Patentlaan 2
NL - 2280 HV Rijswijk
Tel. (+31-70) 340-2040, Tx. 31 651 eponi,
Fax (+31-70) 340-3018

Authorized officer

Petter, E

INTERNATIONAL SEARCH REPORT

Int'l. Patent Application No.

PCT/GB 99/04189

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

| Category * | Citation of document, with indication, where appropriate, of the relevant passages | Relevant to claim No. |
|------------|---|-----------------------|
| X | US 4 966 144 A (ROCHKIND SIMEONE ET AL) 30 October 1990 (1990-10-30) abstract | 42 |
| P, X | WO 99 62599 A (ORON AMIR) 9 December 1999 (1999-12-09) abstract | 42 |

INTERNATIONAL SEARCH REPORT

International application No.

PCT/GB 99/04189

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☒ Claims Nos.: 32-41
because they relate to subject matter not required to be searched by this Authority, namely:
Rule 39.1(iv) PCT -Method for treatment of the human or animal body by therapy
2. ☐ Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:
3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this International application, as follows:

1. ☐ As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest.
- ☐ No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

information on patent family members

Inter. Application No

PCT/GB 99/04189

| Patent document cited in search report | Publication date | Patent family member(s) | Publication date |
|---|---------------------|--|--|
| WO 9830283 A | 16-07-1998 | US 5951596 A AU 5918898 A NO 993410 A | 14-09-1999 03-08-1998 06-09-1999 |
| DE 29515096 U | 30-11-1995 | WO 9636396 A EP 0825889 A EP 0906771 A EP 0935980 A EP 0934759 A | 21-11-1996 04-03-1998 07-04-1999 18-08-1999 11-08-1999 |
| DE 2826353 A | 20-12-1979 | NONE | |
| DE 4113803 A | 29-10-1992 | NONE | |
| US 4966144 A | 30-10-1990 | IL 82830 A | 29-03-1992 |
| WO 9962599 A | 09-12-1999 | NONE | |

**This Page is Inserted by IFW Indexing and Scanning
Operations and is not part of the Official Record**

BEST AVAILABLE IMAGES

Defective images within this document are accurate representations of the original documents submitted by the applicant.

Defects in the images include but are not limited to the items checked:

- ☐ BLACK BORDERS
- ☐ IMAGE CUT OFF AT TOP, BOTTOM OR SIDES
- ☒ FADED TEXT OR DRAWING
- ☒ BLURRED OR ILLEGIBLE TEXT OR DRAWING
- ☐ SKEWED/SLANTED IMAGES
- ☐ COLOR OR BLACK AND WHITE PHOTOGRAPHS
- ☐ GRAY SCALE DOCUMENTS
- ☐ LINES OR MARKS ON ORIGINAL DOCUMENT
- ☐ REFERENCE(S) OR EXHIBIT(S) SUBMITTED ARE POOR QUALITY
- ☐ OTHER: _____

IMAGES ARE BEST AVAILABLE COPY.

As rescanning these documents will not correct the image problems checked, please do not report these problems to the IFW Image Problem Mailbox.